

Artisan's Asylum Reusable Face Shield - Instructions for Use

These instructions for use correspond to **Revision 2** of the **Artisan's Asylum Reusable Face Shield**.

These Instructions for Use must be communicated to the End User of the Device

Appropriate Use Criteria

This supplementary face shield was created as an emergency action in effort to provide protection as a backup Personal Protective Equipment (PPE) option if the traditional PPE devices have become unavailable. This device has not gone through the same regulatory approval process as traditional PPE, but has gone through a special verification process expedited strictly for the response to the COVID-19 pandemic.

This device is intended to be use only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act).The decision to implement this device should be made with careful consideration and under the consultation of the corresponding institution's occupational health and infection control departments.

A laser cut or 3D printed shield frame that can adapt to a variety of shield designs. The device is a face shield that can be fully autoclaved. Device was designed to follow ANSI standards Z87.1 and autoclave best practices.

The designer of this device does not warrant or guarantee efficacy, use at your own discretion.

The information included in this document provides device description and feature overview, recommended assembly steps, and cleaning instructions for reuse.

Device Overview

A laser cut or 3D printed shield frame that can adapt to a variety of shield designs. Originally based off of the Scale Workspace reusable face shield, but optimized for mass production due to near tessellation of the print. Nesting the frames enables significant cycle time improvements. Currently produced in Somerville, MA (near Boston, MA) at Artisan's Asylum and provided to local health groups for testing. The original design that this design is based on, has been produced in New Orleans and provided to Ochsner in excess of 1350 QTY shipped and heavily tested.

Features:

- Top section covered to prevent droplets from above the forehead
- Sub 1 minute laser cut times out of 1/8" Polypropylene on a 100W laser
- Space for safety goggles, and a respirator
- Access for a stethoscope
- All materials are industry standard for autoclave sterilization (and UV safe, bleach safe, etc..)

The FDA has authorized production of protective face shields outside of the normal clearance pathway during the Covid-19 pandemic, based on Part 5, section D of the “Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency Guidance for Industry and Food and Drug Administration Staff.

This face shield has undergone review in a clinical setting and is recommended when fabricated as instructed.

Device to be disinfected per CDC guidelines, ideally this device is sterilized with steam treatment. Dispose of rubber bands between uses, the silicone comfort strip, polypropylene frame and polycarbonate visor may all be sterilized in typical medical autoclave. The author and designer of this device prefers using a dishwasher as that is the most convenient.

See Appendix A for recommended disinfecting solutions and sterilization methods for this device.

See Appendix B for guidelines on material selection.

Components to be disposed of after every use or immediately after potential contamination by bodily fluids

- Elastic band

Components to be disinfected and reused:

- Frame
- Visor
- Comfort strip



Fig. 1: Fully assembled shield

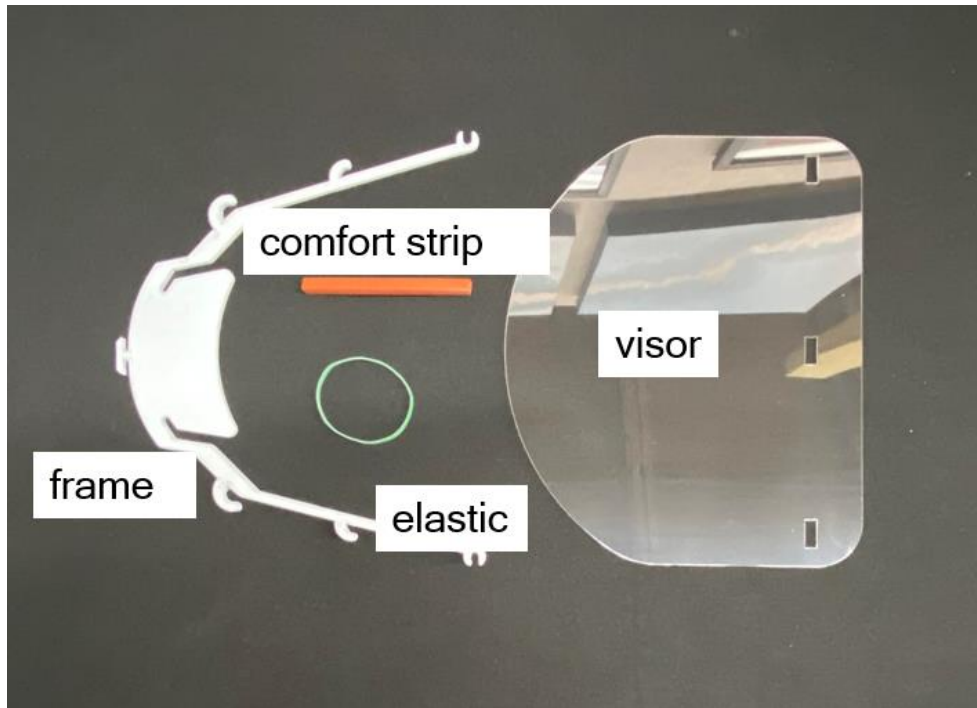


Fig. 2: Fully disassembled shield

Point of Care Assembly and Cleaning Instructions

For instruction on how to properly assemble, clean, and reassemble for reuse of the Artisan's Asylum reusable face shield, please refer to the steps outlined below.

Assembly Steps



Instructions for Assembling A² Reusable Face Shield

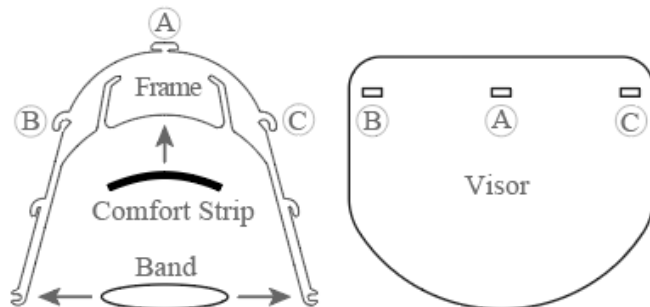


1. Attach comfort strip to center inside portion of frame.
2. Slot visor hole (A) onto frame tab (A).
3. Bend visor to slot hole (B) into tab (B), repeat for (C).
4. Flex arms of frame inward to secure visor, and attach band.
5. Cover slits in frame with medical tape if needed.

Note: All supplied materials are latex free. Product may have burns or burrs due to fabrication. These do not affect sterility.



<https://youtu.be/seS3nvT-KgY>



Assembly instructions available on YouTube:

<https://www.youtube.com/watch?v=seS3nvT-KgY>

CDC PPE SELECTION:

<https://www.cdc.gov/hai/pdfs/ppe/ppeslides6-29-04.pdf>

Recommended Cleaning

The recommended materials selected for making the reusable components of this reusable shield have a proven track record for remaining stable during and after the use of the list of disinfectants and sterilization process outlined in Appendix A. However, there has been no formal testing completed yet to support the claim that the use of disinfectants alone is a sufficient cleaning approach against the COVID19 virus specifically on the surface of this material.

Because of this, it is recommended that the following disinfection and sterilization steps are performed after each user is finished using the face shield and the user has followed the proper procedures for doffing the device.

Appendix A: Recommended Disinfectants and Sterilization Methods

From FDA guidelines on [Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#) released March 2020 it is recommended that “this policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act)”. The policy recommends to use an approved disinfection agent as it should “minimize the viability of SARS-CoV-2” on the surface of the Artisan’s Asylum Reusable Face Shield.

Recommended Disinfecting Agents:

From the [EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2](#), it is recommended to use the following solutions for the disinfecting procedures of this device.

Bleach, 3% Sodium Hypochlorite by Volume (20:80 dilution of bleach solution)
Windex, ammonia based
Soap and Water

Recommended Sterilization Method:

Below is a table outlining the sterilization parameters that are recommended to be used for autoclave sterilization processing.

Dishwasher:

- Disassemble all components
- Run all components aside from elastic bands on a heavy wash or sanitization setting.

Autoclave:

- Disassemble shield, consult the following chart for material compatibility before using an autoclave

	Autoclave material choice	
	Safe Materials	Unsafe Alternative Materials
Visor	Polycarbonate (PC)	Polyethylene Terephthalate (PET), Cellulose Acetate
Frame	Polypropylene (PP), Polycarbonate (PC)	High Density Polyethylene (HDPE)
Elastic	Silicone O-ring (VMQ)	Synthetic Rubber Band, hair elastic
Comfort Strip	Silicone edging (VMQ)	Anything with adhesive, most foams, etc...

- Place autoclave compatible materials in the autoclave, **CAUTION: consult your autoclave manual and autoclave owner to check material compatibility.**
- Parameters: 25min steam sterilization at 121C

Appendix B: Recommended Materials

Frame:

- 1/8" Polypropylene (if 3D printed, suggest PC filament for autoclave use)

Visor:

- 0.01"- 0.02" Polycarbonate (PC)
- 0.01" – 0.02" Polyethylene terephthalate (PET or PET-G) **DO NOT AUTOCLAVE**
- 0.01" – 0.02" Polyvinyl Chloride (PVC) **DO NOT AUTOCLAVE**

Comfort strip (OPTIONAL)

- Silicone, e.g. McMaster #4869A2

Elastic

- Silicone O-ring
- Elastic hair tie
- Latex free rubber bands

Appendix C: Materials in Direct Contact with Skin

Silicone comfort strip

Elastic band (hair tie, latex-free rubber, or silicone)

Polypropylene frame

The biggest area of concern is the elastic band, for individuals with latex allergies or sensitivities, caution should be used in selecting this material.